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10/563,567	01/06/2006	Shigeru Nemoto	KITO8.001APC	3671

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EXAMINER	
CAMPBELL, VICTORIA P	

ART UNIT	PAPER NUMBER
4123	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/563,567	NEMOTO, SHIGERU	
	Examiner	Art Unit	
	VICTORIA P. CAMPBELL	4123	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *06 January 2006* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/9/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This is the initial Office Action based on the 10/563,567 application filed January 6, 2006, which is a National Stage entry of PCT/JP04/09557, filed July 6, 2004, and which claims priority to Japan Patent Application 2003-193101, filed July 7, 2003. Claims 1-20 as originally filed are currently pending and considered below.

Information Disclosure Statement

1. The listing of references in the specification is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

2. The information disclosure statement filed May 9, 2006 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein, *that has been crossed out,* has not been considered.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the "holder pivot support mechanism" of claim 2, claim 5, and claim 18 must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

4. The drawings are objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: Fig. 4b, #417 and Fig. 10, #S11. Corrected drawing sheets in compliance

with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

5. The drawings are objected to because Figs. 7a and 7b are said on page 9, line 24-25 of the specification to show liquid syringe 200, however, the drawings depict cylinder member 210. Additionally, page 15, line 15 says that the display will read "Syringe mounted" in step S2, but Fig. 10 says the display will read "Syringe present". Page 15, lines 18-19 says that the display will read "Syringe not mounted" in step S3, but Fig. 10 says the display will output "Syringe not present". Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary,

the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

6. The disclosure is objected to because of the following informalities:

Page 12, line 7 reads "Adaptor body 401 have a lower surface" but should read --Adaptor body 401 has a lower surface--.

Page 16, line 23 reads "guidance as 'Syringe not mounted appropriately.'" but should read –guidance such as "Syringe not mounted appropriately."—

Page 18, lines 9-10 are vague and unclear.

Page 18, lines 16-17 read "so that it can hold appropriately cylinder member 210" but should read –so that it can appropriately hold cylinder member 210--.

Page 19, line 6 reads "cylinder adaptor 200" but should read --cylinder adaptor 400--.

Appropriate correction is required.

7. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

8. Claims 8, 11, 12, and 16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form.

Claim 8 recites that the display panel is provided together with *at least one of* the cylinder holding mechanism and the piston actuating mechanism, both of which are *required* by parent claim 1.

Claim 11 recites that the liquid injector comprises a cylinder holding mechanism, a piston actuating mechanism, and mount-detecting means, all of which are provided for by claim 1.

Claim 12 recites the cylinder adapter comprises an adapter body with outer and inner surfaces and a contact-transfer member, all of which are already set forth by parent claim 3.

Claim 16 recites the liquid injector comprises a cylinder holding mechanism, a piston actuating mechanism, and a switch, all of which are already set forth in parent claim 13.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 1-5 and 7-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over USPGPub 2001/0021823 A1 to Nemoto in view of USPN 5,714,232 to Reilly et al.

12. Regarding claims 1-20, Nemoto discloses the following:

1. A liquid injection system (Fig. 13) comprising a liquid syringe (Fig. 13, #20); and a liquid injector (Fig. 13, #10); the liquid syringe including a cylinder member (Fig. 13, #21) and a piston member (Fig. 13, #23) slidably inserted into the cylinder member, and the liquid injector including a cylinder holding mechanism (Fig. 13, #11) for receiving the cylinder member of the liquid syringe mounted removably thereon and a piston actuating mechanism (Fig. 11, #12, also shown, but not labeled, on Fig. 13) for relatively moving the piston member with respect to the held cylinder member of the liquid syringe [...].

2. […] wherein the cylinder holding mechanism comprises: a pair of left and right movable holders (Fig. 19, #116), each having an arc-shaped groove defined in an inner surface (Fig. 19, seen as the dotted line in movable holder #116), to the groove of which a cylinder flange (Fig. 19, #122) of the liquid syringe with its axis extending forwardly and rearwardly are removably engaged, and a holder pivot support mechanism (Fig. 19, #117) for pivotally supporting each of the movable holders for vertical angular movement between an open position in which the movable holders are open upwardly for allowing the cylinder flange to be inserted into the grooves and a closed position in which the cylinder flange is retained from left and right sides by the grooves (See Figs. 19a and 19b).

3. […] wherein the liquid syringes of various sizes are provided (Paragraph [0005] provides for a smaller size syringe), further comprising at least one cylinder adapter (Fig. 13, #13) for allowing the cylinder holding mechanism to hold the liquid syringe having a size other than the maximum size, wherein the cylinder holding mechanism directly receives the liquid syringe having the maximum size mounted thereon and the liquid syringe having a size other than the maximum size mounted thereon through the cylinder adapter (Paragraph [0005]), and the cylinder adapter comprises an adapter body (Fig. 13, #13) having an outer surface held by the cylinder holding mechanism (Fig. 13, #13, not explicitly shown, but interpreted as the not shown bottom surface of part #13) and an inner surface holding the cylinder member (Fig. 13, #13, not labeled, but interpreted as the upper surface of part #13) […].

5. [...] wherein the cylinder adapter includes: a pair of left and right movable holders (Fig. 19, #116), each having an arc-shaped groove defined in an inner surface (Fig. 19, seen as the dotted line in movable holder #116), to the groove of which the cylinder flange (Fig. 19, #122) of the liquid syringe with its axis extending forwardly and rearwardly are removably engaged, and a holder pivot support mechanism (Fig. 19, #117) for pivotally supporting each of the movable holders for vertical angular movement between an open position in which the movable holders are open upwardly for allowing the cylinder flange to be inserted into the grooves and a closed position in which the cylinder flange is retained from left and right sides by the grooves (See Figs. 19a and 19b). Examiner notes that the prior art states in Paragraph [0005] that the adaptor functions as a cylinder holder for the syringe, and Paragraph [0078] describes Fig. 19 as showing the positioning of a syringe in a cylinder holder equipped with two movable clamps.

7. [...] wherein the liquid injector further includes a display panel (Fig. 41, #15) for outputting as display the detection result of the mount-detecting means.

8. [...] wherein the display panel (Fig. 42, #17) is provided together with at least one of the cylinder holding mechanism and the piston actuating mechanism (Paragraph [0056]).

9. [...] wherein the liquid injector further includes drive control means for controlling the piston actuating mechanism to disable the operation thereof when the mount-detecting means detects no mount of the liquid syringe (Fig. 41, #15).

10. [...] wherein the liquid injector further comprises: an imaging diagnostic apparatus for capturing an image of a patient to whom a liquid is injected from the liquid syringe; and control means for controlling the imaging diagnostic apparatus to disable the operation thereof when the mount-detecting means detects no mount of the liquid syringe (Paragraph [0004] describes potential use of this device with CT, X-ray, and MRI imaging, all of which are controlled by external devices capable of disabling the operation of the device if a proper signal was received).

11. [...] comprising: a cylinder holding mechanism (Fig. 13, #11) for receiving a cylinder member (Fig. 13, # 21) of the liquid syringe mounted removably thereon; a piston actuating mechanism (Fig. 11, #12; also shown, but not labeled, on Fig. 13) for relatively moving the piston member with respect to the held cylinder member of the liquid syringe [...].

12. [...] comprising: an adapter body (Fig. 13, #13) having an outer surface (Fig. 13, #13; lower surface, not shown) held by the cylinder holding mechanism and an inner surface (Fig. 13, #13; upper surface, not labeled) holding the cylinder member [...].

13. A liquid injection system (Fig. 13) comprising: a first liquid syringe (Fig. 13, #20) comprising a cylinder member (Fig. 13, #21) and a piston member (Fig. 13, #23) slidably inserted into the cylinder member; and a liquid injector Fig. 13, #10) comprising a cylinder holding mechanism (Fig. 13, #11) for receiving the cylinder member of the liquid syringe mounted removably thereon, and a piston actuating

mechanism (Fig. 11, #12, also shown but not labeled in Fig. 13) for moving the piston member relative to the cylinder member when the cylinder member is held by the cylinder holding mechanism [...].

14. [...] wherein the liquid injector further includes a computer (Fig. 41, #15) for controlling the piston actuating mechanism to disable the operation thereof when the switch detects no mount of a liquid syringe.

15. [...] wherein the liquid injector further comprises: an imaging diagnostic apparatus for capturing an image of a patient into whom a liquid is injected from the liquid syringe; and a computer for controlling the imaging diagnostic apparatus to disable the operation thereof when the switch detects no mount of the liquid syringe (Paragraph [0004] describes potential use of this device with CT, X-ray, and MRI imaging, all of which require an external control unit which may take the form of a computer).

16. [...] comprising: a cylinder holding mechanism (Fig. 13, #11) for receiving a cylinder member (Fig. 13, #21) of the liquid syringe mounted removably thereon; a piston actuating mechanism (Fig. 11, #12, also shown but not labeled in Fig. 13) for relatively moving the piston member with respect to the held cylinder member of the liquid syringe [...].

17. A liquid injection system (Fig. 13) comprising: a first liquid syringe (Fig. 13, #20) comprising a cylinder member (Fig. 13, #21) and a piston member (Fig. 13, #23) slidably inserted into the cylinder member; and a liquid injector (Fig. 13, #10) comprising a cylinder holding mechanism (Fig. 13, #11) for receiving the

cylinder member of the liquid syringe mounted removably thereon, and a piston actuating mechanism (Fig. 11, #12, also shown but not labeled in Fig. 13) for moving the piston member relative to the cylinder member when the cylinder member is held by the cylinder holding mechanism [...].

18. [...] wherein the cylinder holding mechanism (Fig. 13, #11) comprises: a pair of left and right movable holders (Fig. 19, #116), each having an arc-shaped groove defined in an inner surface (Fig. 19, seen as the dotted line in movable holder #116), the grooves of which are removably engaged by a cylinder flange (Fig. 19, #122) of the liquid syringe; and a holder pivot support mechanism (Fig. 19, #117) for pivotally supporting each of the movable holders for vertical angular movement between an open position in which the movable holders are open upwardly for allowing the cylinder flange to be inserted into the grooves and a closed position in which the cylinder flange is retained from left and right sides by the grooves (See Figs. 19a and 19b).

19. [...] and a cylinder adapter (Fig. 13, #13) for allowing the cylinder holding mechanism to hold the second liquid syringe; wherein the cylinder holding mechanism directly receives the first liquid syringe mounted thereon and receives the second liquid syringe mounted thereon through the cylinder adapter; and the cylinder adapter comprises: an adapter body (Fig. 13, #13) having an outer surface (Fig. 13, #13, unlabeled and not shown lower surface) held by the cylinder holding mechanism (Fig. 13, #11) and an inner surface(Fig. 13, #13, the unlabeled upper surface) holding the cylinder member (Fig. 13, #21) [...].

20. [...] wherein the cylinder adapter further comprises: a pair of left and right movable holders (Fig. 19, #116), each having an arc-shaped groove defined in an inner surface (Fig. 19, seen as the dotted line in movable holder #116), the grooves of which are removably engaged by the cylinder flange (Fig. 19, #122) of the liquid syringe; and a holder pivot support mechanism (Fig. 19, #117) for pivotally supporting each of the movable holders for vertical angular movement between an open position in which the movable holders are open upwardly for allowing the cylinder flange to be inserted into the grooves and a closed position in which the cylinder flange is retained from left and right sides by the grooves (See Figs. 19a and 19b).

13. Nemoto does not appear to explicitly disclose a mount-detecting means or switch on the liquid injector, nor does he describe a contact-transfer member on the adaptor.

However, regarding claims 1, 11, 13, 16, and 17, Reilly et al discloses the following:

1. [...] wherein the liquid injector comprises mount-detecting means for detecting contact and separation of the cylinder member when the cylinder member is mounted on and removed from the cylinder holding mechanism, respectively (Fig. 2, #72).

11. [...] mount-detecting means for detecting contact and separation of the cylinder member when the cylinder member is mounted on and removed from the cylinder holding mechanism, respectively (Fig. 2, #72).

13. [...] wherein the liquid injector further comprises a switch that detects contact

and separation of the cylinder member when the cylinder member is mounted on and removed from the cylinder holding mechanism, respectively (Fig. 2, #72).

16. [...] and a switch that detects contact and separation of the cylinder member when the cylinder member is mounted on and removed from the cylinder holding mechanism, respectively (Fig. 2, #72).

17. [...] wherein the liquid injector further comprises mount-detecting means for detecting contact and separation of the cylinder member when the cylinder member is mounted on and removed from the cylinder holding mechanism, respectively (Fig. 2, #72).

Nemoto and Reilly et al are analogous art because they are from the same field of endeavor/problem solving area of automatic injection syringes. At the time of the invention, it would have been obvious to one of ordinary skill in the art, having the teachings of Nemoto and Reilly et al before him or her to modify the liquid injection system of Nemoto to include the detection switch of Reilly et al because the detection switch of Reilly et al can not only be used to confirm the presence of a syringe, but also to detect particulars about its contents (Reilly et al, Col. 6, 35-41). Therefore, it would have been obvious to combine Nemoto with Reilly et al to obtain the invention in the instant claims.

Furthermore, regarding claims 3, 4, 12, and 19, both Nemoto and Reilly et al fail to explicitly disclose a contact-transfer member disposed on the adaptor and biased to a position not in contact with the mount-detecting means when a cylinder is not installed within it. The existence of this component of the adaptor is inherent because, without it,

the mount-detecting means would only be able to detect if the adaptor was installed, it would have no means of detecting the cylinder member of the syringe. Thus, the contact-transfer member becomes an inherent part of the adaptor when the adaptor and the mount-detecting means are both present and vital to the operation of the device. (See Figs. 7b, 9a, and 9b. Without contact-transfer member 419, the adaptor, when remaining mounted in the device—as in Fig. 9b—would continue to depress switch 131 as if it were a syringe of maximum size—as seen in Fig. 7b. Thus, the apparatus would be an injection system for detecting the mount and dismount of a cylinder adaptor, not a liquid syringe.)

14. Claim 6 is rejected under 35 U.S.C. 103(a) as being unpatentable over Nemoto and Reilly et al in further view of "Hospital Details Failures Leading to MRI Fatality" by Archibold, published August 22, 2001 in the New York Times.

Nemoto and Reilly et al disclose all of the limitations of claim 3 as described above, but fail to explicitly disclose use of non-magnetic materials in the device adaptor.

> **6.** [...] wherein components of the cylinder adapter are made of a nonmagnetic material.

However, Archibold discloses that even heavy (6.5 pound) magnetic objects can be pulled into the magnetic field of an MRI machine (Paragraph 2), becoming a fatal projectile (Paragraph 1). An MRI machine is a device that can perform angiography, a procedure disclosed by Reilly et al as a use for their medical injector (Col. 1, the invention of the patent is described as having improvements over other angiographic injectors). Therefore, it would have been obvious to combine the suggestion to use

nonmagnetic materials appearing in the Archibold article with the teachings of Nemoto and Reilly et al to obtain the invention in the instant claim because such would prevent the existence of fatal projectiles near the MRI machine.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTORIA P. CAMPBELL whose telephone number is (571)270-5035. The examiner can normally be reached on Monday-Thursday, 7-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joe Del Sole can be reached on 571-272-1130. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

VPC

/Joseph S. Del Sole/

Supervisory Patent Examiner, Art Unit 4123